



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,685	03/09/2004	Peter M. Bonutti	782-A04-026	4865

33771 7590 11/17/2006

PAUL D. BIANCO: FLEIT, KAIN, GIBBONS,
GUTMAN, BONGINI, & BIANCO P.L.
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
----------	--------------

3731

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No.

10/797,685

Applicant(s)

BONUTTI ET AL.

Examiner

Julian W. Woo

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-15, 17-33 and 35 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 16 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/9/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 11, 17, and 23 are objected to because of informalities, which can be corrected as follows: In claim 11, line 2, "removable" should be replaced by – removably--. In claim 17, line 8, "control" should be replaced by –controller--. In claim 23, line 2, --of—should be inserted after "attaching." Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 19, it is not certain whether the retainer is part of the invention, since it is said to be "positioned between the tip portion of the end effector and the end portion of the tubular section."

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, 11, 12, 15, 17-22, 27, 28, 30, 33, and 35 rejected under 35 U.S.C. 102(b) as being anticipated by Mollenauer et al. (6,077,277). Mollenauer et al.

Art Unit: 3731

disclose, at least in figures 1 and 6-10 and in col. 5, line 5 to col. 6, line 21; a surgical device for attaching a retainer (76) to a suture (75), where the device includes a first member (54) including a first compression element (61), a second member (55) including a second compression element (56) that is movable in relation with the first member from a first position (see fig. 8) to a second position (see fig. 9), a suture retainer (8), and an external energy source (electrical power via 21 or 25), where the first and second compression elements are configured to receive the retainer; where the second member comprises a tubular section with proximal and distal ends, the proximal end including a gapped portion (58) integrated with the second compression element; where the second member comprises an actuation member (67), where the suture tensioner comprises a bias member (9), where the second member is removably attachable to the first member (at assembly or disassembly of the device), where the energy is contact heating energy, where the device includes a handle assembly (at 67) and a controller assembly (62), where the handle assembly includes a handle portion (67) and an end effector (56) with a tip portion for transmitting energy to the retainer, where the controller assembly includes a controller (65) and a tubular section (54) having an end portion configured for receiving the retainer (at 61), where the handle assembly (at 67) is slidably positionable through the controller assembly, where the tip portion of the end effector comprises a protrusion (56), where the end portion of the tubular section is configured to capture a second section of the retainer, and where the suture tensioner is positioned on the tubular section (e.g., at slot 58). With respect to claims 3-5, the device is deemed to have element 55 as a first member that is

Art Unit: 3731

positioned through a tubular section of the second member (54), where the second compression element (61) is configured to receive a first portion of the retainer, preventing movement of the first portion of the retainer (at compression); and where the first compressive element is configured to capture a second portion of the retainer, such that the second portion is separate from the first portion (i.e., strands of the retainer are separate before heating) when the second member is moved from the first position to the second position.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 10 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. Mollenauer et al. disclose the invention substantially as claimed. Mollenauer et al. disclose that the bias member is used to snare a suture and impart tension on the suture upon proximal movement of the bias member, but they do not

Art Unit: 3731

disclose that the bias member imparts tension of between 2 lbs. to 10 lbs. on the suture. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the bias member, so that it imparts a tension as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

7. Claims 13, 14, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. in view of Bregen et al. (5,306,280). Mollenauer et al. disclose the invention substantially as claimed, but do not disclose an internal energy source disposed within a handle portion of the first member, where the internal energy source is a rechargeable battery. Bregen et al. teach, at least in figure 4 and in col. 5, lines 57-68, a similar surgical device having an internal energy source disposed within a handle portion, where the energy source is a rechargeable battery (39). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Bregen et al., to modify the device of Mollenauer et al. so that it has an internal energy source that is a rechargeable battery. Such a source would allow portability of the device during its use without any physical interference from an attached power cord.

Allowable Subject Matter

8. Claims 7, 8, 16, and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 23-26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a surgical device including, inter alia, a first and second members with first and second compression elements, a suture tensioner, an energy source, a handle assembly, and a controller assembly; where the second member includes a tubular section, a gapped portion, and an actuation member including a bias member biasing the tubular section into a first position, where the first member is configured to transmit at least two different types of energy from the energy source, and where a controller of the controller assembly includes a latch for removable attaching of the controller to the handle.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Egan et al. (5,893,880) and Westhaver et al. (6,669,705) teach devices for joining suture portions together.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-

Art Unit: 3731

4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

November 13, 2006